No. 98-1152

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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REPLY BRIEF FOR THE PETITIONERS

Respondents do not challenge here the findings that led FDA to conclude that the nicotine in tobacco products is intended to affect the structure or function of the body. In particular, respondents do not dispute that (1) the nicotine in tobacco products is highly addictive and acts as a sedative, stimulant, and appetite suppressant, (2) consumers use tobacco products predominantly for those purposes, (3) manufacturers have known for years that consumers use their products predominantly to obtain nicotine's pharmacological effects, (4) manufacturers have privately referred to nicotine as a drug and cigarettes as devices for delivering that drug, and (5) they have long engineered their products to deliver to consumers the precise doses of nicotine they need to obtain its powerful effects. Gov't Br. 3-8. The sole question presented therefore is whether, given those unchallenged findings, tobacco products are drug-delivery devices within the meaning of the FDCA. As we show in our opening brief, FDA reasonably concluded that they are.

A. Structure/Function Definitions

1. a. Respondents contend (RJR Br. 11-13) that a product falls within the structure/function definitions only if a manufacturer makes a structure/function "claim." The term "claim," however, does not appear in the definitions. Instead, those definitions encompass as "drugs" and "devices" products that are "intended" to affect the structure or function of the body, 21 U.S.C. 321(g)(1)(C) and (h)(3), and "intended" simply does not mean the same thing as "claimed." The dictionary definition of "intend" is "to have in mind as a design or purpose." *Webster's Third New International Dictionary* 1175 (1986). The Court long ago stated that "[t]he law presumes that every man intends the legitimate consequence[s] of his own acts," *Agnew* v. *United States*, 165 U.S. 36, 53 (1897), and more recently, it interpreted "primarily intended for use" in an analogous statutory context as "the item's likely use." *Posters 'N' Things Ltd.* v. *United States*, 511

U.S. 513, 521 (1994). In contrast, the definition of "claim" is "an assertion, statement, or implication (as of value, effectiveness, qualification, eligibility)." *Webster's Third* at 414. Where a provision of the FDCA is meant to turn on such representations, it specifically so provides. Gov't Br. 26.

Because manufacturers ordinarily have a financial incentive to make claims about a product so that customers will be be induced to buy it, the claims that are made in connection with a sale *usually* reflect a product's "intended" effects. In some cases, however, manufacturers can count on consumers to understand the uses and pharmacological effects of a product, and to buy it for those reasons, even in the absence of any claims by the manufacturers. In such cases, FDA is not powerless to protect the public health. It may treat those products as drugs or devices when it finds, based on all the objective evidence, that the pharmacological effects of the product are "intended." That is the situation here: The evidence convincingly shows that the nicotine in tobacco products is intended to be used by consumers to sustain addiction and for sedation, stimulation, and weight control. It would be contrary to the fundamental public health purposes of the Act to conclude that a product is altogether excluded from regulation (even to prevent its adulteration or to improve its safety) precisely *because* its drug-like attributes are so widely known and thoroughly embedded in the behavior of consumers and manufacturers as to render claims to that effect superfluous. Gov't Br. 25.

Even respondents shrink from that consequence of their position, for they concede that FDA could regulate a product such as Prozac if it were sold only by its name, without any representations about its uses or pharmacological effects. Respondents would reach that result, however, on the theory that the product name has taken on a "secondary meaning" that constitutes an "implied claim" about the product's uses and effects, attributes they say tobacco products do not have. RJR Br. 15; B&W Br. 24-25. We disagree that tobacco

products do not have similar attributes. But there is no need to resort to concepts such as "secondary meaning" or "implied claim" (which do not appear in the Act) to ensure that a product marketed simply as Prozac is covered by the FDCA. The reason the Act applies in that example is that consumers would be aware of the uses and effects of the product based on its name alone, they would buy and use the product accordingly, and manufacturers could count on them to do so. The same is true for tobacco products.

Respondents' claims-only theory threatens to open a gaping hole in the Act's protection of the public health. Under respondents' theory, manufacturers of potent drugs could escape regulation by marketing their products with the same chemical name as a brand name product, but without accompanying drug claims. A manufacturer could freely market in that manner such drugs as "fluoxetine" (the chemical name for the compound in Prozac) and "sildenafil citrate" (the chemical name for the compound in Viagra), and FDA would be unable to assure their safety or effectiveness.[1]

b. Respondents' claims-only interpretation also conflicts with FDA's "intended use" regulations, which have been in effect since 1952. See Gov't Br. 26-27 & n.5. Those regulations, which are entitled to deference under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and are not challenged here, provide that "intended use" refers to the "objective intent" of the person legally responsible for the labeling, not to that person's "claims." 21 C.F.R. 201.128 (drug), 801.4 (device). The regulations do provide that a manufacturer's "labeling claims"

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[1] Respondents concede (RJR Br. 15) that under their theory, nicotine inhalers would escape FDA review as long as the manufacturer promoted them for "breathing pleasure." In an attempt to avoid that anomaly, respondents suggest that the Consumer Product Safety Commission could regulate that product. Yet respondents offer no reason why Congress would have wanted a product that manufacturers intend and consumers use as a drug-delivery device, and that poses the health risks of such a device, to be regulated by an agency with no expertise in that area.

and "advertising matter" can constitute evidence of "objective intent." *Ibid.* The regulations make clear, however, that such evidence is not the exclusive basis for determining that intent. Also relevant are: (1) all of the manufacturer's "oral or written statements," (2) "the circumstances surrounding" a product's distribution, (3) the manufacturer's "knowledge" that a product is "offered and used for a purpose for which it is neither labeled nor advertised," and (4) the manufacturer's "knowledge of facts that would give him notice" that a product "is to be used" for purposes other than those for which the manufacturer offered it. *Ibid.* As FDA has explained, the "intended use" regulations contemplate that FDA will consider "all of the relevant evidence" and decide, "from the perspective of a reasonable fact-finder," whether the product is intended to affect the structure or function of the body. 61 Fed. Reg. 45,153 (1996).

Respondents' "claim" requirement also conflicts with FDA's regulatory practice. Products regulated without market claims include "caine," a street drug marketed as incense; "khat," a stimulant; cosmetics containing hormones; toothpaste containing fluoride; interferon; a food supplement containing thyroid; and novelty condoms. Gov't Br. 29-30. Respondents' effort (B&W Br. 26-27) to distinguish those regulatory measures does not accord with FDA's authoritative explanations for its actions. See 61 Fed. Reg. at 45,186-45,191; 60 Fed. Reg. 41,527-41,531 (1995).

c. There is no merit to respondents' contention (RJR Br. 15-17; B&W Br. 28-32) that FDA's longstanding interpretation will interfere with physicians' ability to prescribe approved drugs and devices for uses other than those on the labeling and inhibit the development of new uses for approved products. FDA does not prohibit physicians from prescribing approved products for off-label uses. Insofar as the manufacturer is concerned, however, FDA regulations have provided ever since 1938 that, unless FDA grants an exception, labeling should contain adequate directions for

those purposes for which a drug or device is "commonly used," even if the manufacturer has not chosen to promote those purposes in its labeling or advertising.[2] When a particular off-label use becomes widespread, FDA may fairly "impute the requisite intended use[] to [the] manufacturers" (J.A. 62). As FDA explained in 1972, when that occurs, "FDA will investigate it thoroughly" and "take whatever action is warranted to protect the public," including, if appropriate, "[r]equiring a change in the labeling to warn against or approve the unapproved use, seeking substantial evidence to substantiate its use [as safe and effective], restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases." 37 Fed. Reg. 16,504 (1972) (quoted at 61 Fed. Reg. at 45,182); see, *e.g.*, 64 Fed. Reg. 10,994 (1999) (addressing off-label use of diet drug in "Phen Fen," which resulted in serious cardiac events); B&W Br. 31 (labeling requirement for baby aspirin used by adults to reduce heart attack risk). These steps do not interfere with the practice of medicine or the proper development of new uses for approved drugs or devices.

d. Respondents derive (RJR Br. 12; B&W Br. 11-12) their non-textual "claim" requirement from a single sentence in a 1934 Senate Report stating that "[t]he manufacturer of the article through his representations in connection with its

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[2] Those regulations specify what constitutes "adequate directions for use" in the labeling of a drug or device under 21 U.S.C. 352(f)(1). They provide that, absent an exception, such directions must be adequate for the purposes for which the drug or device "is intended" (cross-referencing the "intended use" regulation), and then state that directions may be inadequate if they omit statements of "all conditions, purposes or uses for which the drug [or device] is intended"—"including" not only those for which it is "prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising," but also those for which it "is commonly used." 21 C.F.R. 201.5 (drugs), 801.5 (devices). That requirement, adopted in its current form in 1952 (17 Fed. Reg. 6818 (1952) (21 C.F.R 1.106(1)), derives from a regulation adopted in 1938. See 3 Fed. Reg. 3167 (1938).

sale can determine the use to which the article is to be put." S. Rep. No. 493, 73d Cong., 2d Sess. 3 (1934). That sentence, however, says only that representations "*can* determine" an article's intended use, not that the presence or absence of a representation is always dispositive.[3]

By contrast, FDA's longstanding position that "intended" effects are not limited to manufacturer claims was confirmed by the House Report on the 1976 device amendments. That report specifically rejected the proposition that a claim is dispositive and explained that the Secretary "may consider actual use of a product in determining whether or not it is a device." H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976). Contrary to respondents' assertion (B&W Br. 17 n.14), the 1976 House Report cannot be dismissed on the ground that it "interprets language enacted 38 years earlier," because the structure/function "device" definition was reenacted in the 1976 amendments. Gov't Br. 27.[4]

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[3] Respondents also take the sentence entirely out of context. It is part of a paragraph discussing when a product that is concededly subject to the Act will be regulated as either a "drug" or a "food" (or both). The sentences preceding the one respondents quote explain that "if [the product] is to be used *only* as a food it will come within the definition of food and none other," while "[i]f it contains nutritive ingredients but is sold for drug use *only*, as *clearly* shown by the labeling and advertising, it will come within the definition of drug, but not that of food"; the sentence immediately following the one respondents quote then states that a manufacturer of a laxative that is a medicated candy or chewing gum could bring its product within the definition of drug "and escape that of food" by "representing the article *fairly* and *unequivocally* as a drug product." S. Rep. No. 493, at 3 (emphasis added). The paragraph as a whole thus suggests no more than that a manufacturer, by "clearly," "unequivocally," and "fairly" representing a product as "only" one thing (*e.g.*, a drug), can negate the conclusion that it is another (*e.g.*, a food). Here, respondents have carefully avoided making claims that reflect the intended uses of their products. Nor have they made claims that their products are intended only for some *other* use that negates their status as drugs or devices, and such claims could not "fairly" be made, in light of the overwhelming evidence of intended pharmacological effects. Compare Gov't Br. 27-28.

[4] Respondents' effort (B&W Br. 12-15) to find support for their position in the Drug Amendments of 1962 is unavailing. The 1962 amendments prevent a drug manufacturer from making claims about a new product, or new claims about an existing product, without first establishing that the product is effective or generally recognized as such. See *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 622 (1972). Specifically, they require manufacturers to establish that a new drug will have the effect it purports or is represented to have under the conditions "prescribed, recommended, or suggested" in its labeling. 21 U.S.C. 355(d)(5), (e)(3). In justifying that requirement, several committee reports, Members of Congress, and administration witnesses stated that drugs should be shown to be effective for their "intended" uses or purposes before they are marketed. See B&W Br. 13-15.

The quoted passages did not advert to the wholly different situation, presented here, of a product that has been marketed for many years and whose "intended" effects are shown by pervasive practices of consumers and manufacturers, without any need for claims. None of those passages purported to interpret the structure/function definition or to equate "intended" effects in that definition with uses "prescribed, recommended, or suggested" on the labeling in 21 U.S.C. 355(d). Indeed, the 1962 amendments establish that Congress did *not* equate those two concepts. Section 107(c)(4) of the amendments afforded grandfather protection for a drug "when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to that drug" prior to the amendments' effective date. 76 Stat. 789; see *USV Pharmaceutical Corp.* v. *Weinberger*, 412 U.S. 655 (1972). That clause plainly contemplates that there can be "intended uses" other than those identified in the labeling. See H.R. Rep. No. 2464, 87th Cong., 2d Sess. 12 (1962). After the 1962 amendments, as before, if an approved drug develops such a use—*i.e.*, if the drug becomes commonly used for an off-label purpose—FDA can respond in various ways, including by requiring that the labeling contain adequate directions for that additional use. See pp. 4-5, *supra*. If FDA imposes such a requirement, then conditions for that additional use will be "prescribed, recommended, or suggested" in the labeling, and that use will therefore have to satisfy the new drug standards of safety and effectiveness. See 21 U.S.C. 321(p)(1), 355(d)(1) and (5), 355(e)(1) and (3).

e. In sum, the text, legislative history, and administrative interpretation of the Act all make clear that intended effects under the drug and device definitions are not limited to those claimed by manufacturers. And numerous judicial decisions, including many cited by respondents (RJR Br. 12, 14, B&W Br. 11-12, 21-24), confirm that intent may be determined from "any relevant source," including consumer use. Gov't Br. 28.

2. Respondents err in contending (UST Br. 9) that the structure/function definitions are limited to products with a medical purpose. The term "medical purpose" does not appear in the Act's definitions, and there is no term in the definitions that could serve as the basis for such a limitation.

Moreover, the drug and device definitions include as separate categories (1) products "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," and (2) products "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1) and (h). Since the dictionary defines "medical" as "of, relating to, or concerned with physicians or with the practice of medicine," *Webster's Third* at 1402, and "medicine" as "a substance or preparation used in treating a disease," *ibid.*, respondents' medical-purpose gloss on the latter definition would eliminate any meaningful distinction between the two. Congress, however, added the latter definition because certain dangerous and ineffective products that were intended to affect the structure or function of the body, such as weight-loss products, did not fit within the treatment-of-disease category. Gov't Br. 20. If the structure/function definition required proof of a medical purpose, it would resurrect the former regime and reopen the loophole that Congress sought to close.

Respondents' medical-purpose test also conflicts with FDA's practice of regulating products that do not have a medical purpose—tanning booths, wrinkle creams, hair-growing products, stimulants (such as NoDoz), aphrodisiacs, and athletic performance enhancers. 61 Fed. Reg. at 44,677-44,678. Respondents seek to reconcile their medical-purpose test with that FDA practice by equating a medical purpose with a purpose to produce a beneficial effect on the body (UST Br. 28-30). But if that is the relevant inquiry, tobacco products qualify. "Tobacco industry scientists have themselves argued that tobacco products provide 'needed physiological benefits (increased mental alertness; anxiety reduction, coping with stress)," and that "nicotine is a very remarkable beneficent drug." 61 Fed. Reg. at 44,680.[5]

3. Respondents contend (RJR Br. 21) that, because Congress has exempted tobacco products from other health and safety statutes, those products should be excluded from the FDCA as well. Respondents have it backwards. The specific exemptions in other statutes demonstrate that Congress knows how to exempt tobacco products when it wants to. Since Congress did not exempt tobacco products from the "drug" and "device" definitions in the FDCA (even though it did exempt tobacco from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1)), those products are covered by the FDCA—if, as FDA has found, they are "intended to affect the structure or any function of the body."[6]

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[5] Respondents contend (UST Br. 15; RJR Br. 18) that without a "medical claims" limitation, products such as guns, thermal clothing, air conditioners, exercise equipment, scuba-diving gear, mattresses, and even roller coasters and horror movies could be considered "devices" under the Act. FDA has never interpreted the FDCA to reach any of those products, cf. *Church of the Holy Trinity* v. *United States*, 143 U.S. 457, 459 (1892), and it plainly would have discretion not to take enforcement action even if they were thought by some to be covered. *Heckler* v. *Chaney*, 470 U.S. 821 (1985). If FDA nonetheless attempted to regulate such products, the question would arise whether it would be reasonable to press the words of the structure/function definition to the point of treating as "devices" products that do not deliver drugs to the body, that do not have intended effects similar to any other product regulated by FDA, and that implicate more directly the consumer-safety purposes of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051 *et seq.*, than the health concerns of the FDCA (see RJR Br. 19; B&W Br. 20-21 n.17). This case does not remotely raise that question. Tobacco manufacturers have themselves characterized nicotine as a powerful drug and cigarettes as devices for delivering nicotine to the body; the intended effects of tobacco products are the same as many other products regulated by FDA (Gov't Br. 23-24), and tobacco products directly implicate the health concerns of the FDCA.

[6] Respondents assert (RJR Br. 19-20) that the exemption in the CPSA for tobacco products is superfluous if they are drugs or devices under the FDCA, because there is a separate exemption in the CPSA for FDCA drugs and devices. When Congress enacted the CPSA in 1972, however, FDA had not yet found sufficient evidence that tobacco products are in-

4. Contrary to respondents' assertion (B&W Br. 9-10; PM Br. 7), FDA's predecessor agency did not announce in 1914 that it could not regulate tobacco products unless they were marketed with medical claims. The agency stated that "tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act," and that "tobacco and its preparations which are not so labeled *and are used for smoking or chewing or as snuff and not for medicinal purposes* are not subject to the provisions of the act." See Gov't Br. 41 n.10. That statement, concerning the treatment-of-diseases definition now in 21 U.S.C. 321(g)(1)(B), indicates that, while health claims are *sufficient* to subject tobacco products to coverage, they are not *necessary*. Indeed, the italicized portion—which would be superfluous under respondents' reading of the Act—reinforces FDA's position that consumer use of a product can support a finding of "intended" effects even in the absence of claims.

Respondents also rely (RJR Br. 13 n.12; B&W Br. 19-20) on statements by FDA officials during the 1960s and 1970s that tobacco products were not covered by the FDCA. Those statements were made in the context of growing

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tended to affect the structure or function of the body. An express exemption was therefore necessary to exclude tobacco prodcuts from the CPSA.

Respondents also argue (RJR Br. 20) that, because the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, includes FDCA "drugs" and excludes "tobacco," 21 U.S.C. 802(6), (12), if the nicotine in tobacco products is a "drug," then it would simultaneously be included and excluded from the definition of "controlled substance." There is no such contradiction. Under familiar principles of statutory construction, the CSA's specific exclusion of "tobacco" prevails over its general inclusion of "drugs." Nor does the CSA's definition of "controlled substance" to mean both "drugs" and "any other substance" included in one of the CSA schedules (see 21 U.S.C. 802(6)) contradict our contention that products taken into the body for pharmacological effects have the classic characteristics of products subject to FDA regulation. The reference to "any other substance" simply permits certain substances to be controlled even without a showing that they are intended to be used as drugs.

awareness, sparked by the Surgeon General's 1964 Report, that tobacco products cause cancer and other serious health conditions. The statements reflected FDA's view that it did not have jurisdiction to regulate tobacco products based on those adverse health effects alone: because consumers used tobacco products in spite of, not because of, their cancer-causing and other harmful properties, *those* effects on the structure or function of the body were not "intended" within the meaning of the FDCA. Cf. *Personnel Administrator* v. *Feeney*, 442 U.S. 256, 279 (1979). The statements also reflected FDA's belief that, absent manufacturer claims, there was then insufficient evidence to warrant the conclusion that tobacco products were "intended" to affect the structure or function of the body in some *other* way.

FDA did not have such evidence until recently. In 1980, when FDA denied the petition filed by Action on Smoking and Health (ASH) due to the absence of evidence of intended effects (J.A. 50-68), no major health organization had yet determined that nicotine was addictive. By 1994, every leading health organization had concluded that it was. In 1980, evidence did not show that most consumers use tobacco products to sustain addiction and for stimulation and sedation. Evidence developed since 1980 shows that the overwhelming percentage of consumers do so. Most dramatic, recently released internal industry documents show that tobacco manufacturers have long known that consumers use their products for their pharmacological effects and have deliberately engineered them to deliver active doses of nicotine. In 1980, that evidence was not available. Gov't Br. 38-39.[7]

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[7] Respondents err in asserting (PM Br. 25) that FDA's 1980 decision was based on a supposed recognition "that its lack of jurisdiction was inherent in the FDCA and not due to lack of evidence." FDA twice stated that consumer-use of a product as a device could be a basis for finding "intended" effects or use, but that ASH had failed to produce sufficient consumer use evidence. J.A. 56-57, 61-62; see also *id.* at 54, 58. The decision also stated that FDA's statement to Congress in 1965 concerning its lack of jurisdiction was likewise based on an absence of evidence of the

While respondents now launch an "everyone has always known" attack on FDA's decision, respondents' chief executives represented to Congress in 1994, under oath, that the nicotine in tobacco products is not addictive, *Regulation of Tobacco Products: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong., 2d Sess. Pt. 1, at 628 (1994), and that respondents do not engineer their products to deliver active doses of nicotine, *id.* at 542, 544, 558, 598. Respondents continued to make those same assertions in this rulemaking proceeding.[8] And, for more than 30 years, respondents withheld from the public critical information about the intended effects of the nicotine in their products. Gov't Br. 5-7.

B. Structure Of The Act

1. Respondents erroneously contend (RJR Br. 24-25) that FDA cannot regulate tobacco products as drugs or devices because the FDCA provides that drugs and devices must be proven safe, and FDA has not found that tobacco products are safe. At the outset, we note the following: First, FDA has chosen to regulate tobacco products as devices, a choice within its authority when, as here, a product is a combination of a drug and a device. 61 Fed. Reg. at 44,400-44,403.[9] Second, the relevant standard for permitting the sale of a device is that the regulatory controls to be applied must provide a "reasonable assurance of * * * safety"

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requisite intended use. J.A. 57. Respondents similarly quote (PM Br. 23) an ambiguous statement from FDA's 1977 decision (J.A. 44-49) without noting that the D.C. Circuit authoritatively interpreted the 1977 decision as likewise resting on lack of evidence. *ASH* v. *Harris*, 655 F.2d 236, 239 (1980); accord Gov't Br. 38 (quoting FDA brief in D.C. Circuit).

[8] *E.g.*, 61 Fed. Reg. at 44,617, 44,670-44,671, 44,706-44,707, 44,776-44,777, 44,783, 44,789, 44,800, 44,958-44,959, 44,965 44,983, 44,986-44,987, 45,065, 45,067, 45,115, 45,141.

[9] Because FDA has chosen to regulate tobacco products as devices rather than drugs, there is no merit to respondents' contention (RJR Br. 27-28) that, under FDA's theory, tobacco products are "new drugs" that FDA may not permit to be marketed unless approved as safe and effective.

for the device. 21 U.S.C. 360c(a). Third, that determination is made at the end of the classification process, after an expert panel studies the product and makes a recommendation, after FDA issues a proposed rule concerning the appropriate regulatory class and controls for the product, and after the public has an opportunity to comment. 21 U.S.C. 360c(b), (c) and (d). That process is often time-consuming, compare *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 478 n.3, 479-480 (1996), and as respondents concede (RJR Br. 29), the Act does not impose a deadline. Fourth, consistent with its usual practice, FDA decided to apply general controls to tobacco products first, rather than delaying regulation until completion of the lengthy classification process. 61 Fed. Reg. at 44,412.

Respondents contend, however, that, regardless of what additional controls may be imposed in the classification process, FDA will not be able to find that a reasonable assurance of safety exists, and that tobacco products therefore will have to be banned. That result is so unthinkable, respondents argue, that, despite the overwhelming evidence that tobacco products are devices for delivering nicotine to the body, they cannot be drug-delivery devices within the meaning of the FDCA. FDA has reasonably determined, however, that the FDCA does not require a ban on the sale of tobacco products to adults.

In classifying a device, the Act requires FDA to weigh "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). Under that standard, devices that are dangerous in the ordinary sense of that word may be permitted to be sold if FDA finds (as it has, *e.g.*, for certain cancer-treatment products) that the health benefits to those who use them outweigh the risks. Gov't Br. 32. FDA has made such a judgment here. Although FDA decided to prohibit the sale of tobacco products to children, it found that, because so many adults are addicted to the products, it would be more dangerous to the health of those adults and to

the public health overall to remove tobacco products from the market completely than to leave them on the market for adults, subject to the Act's general controls and whatever additional controls may be imposed as a result of the classification process. In particular, FDA found that leaving tobacco products on the market provides health benefits because many addicted adults would suffer from nicotine withdrawal and there would not be adequate pharmaceuticals available for treatment, and because the black-market products that would predictably replace existing tobacco products would be even more dangerous for those users. 61 Fed. Reg. at 44,413. Respondents' assertion (RJR Br. 26) that FDA's judgment rests on factors outside FDA's mission, such as adverse effects on law enforcement, the economy, and society at-large, ignores FDA's rationale.

Even if the Act were to require tobacco products to be banned, however, that would not invalidate FDA's threshold determination that tobacco products are "devices" for delivering the "drug" nicotine. It would mean that Congress might then have to consider whether to amend the Act to permit the continued sale of those drug-delivery devices, just as it permitted the continued sale of products containing saccharin after FDA concluded that the Act required them to be banned. Gov't Br. 36-37. Respondents assert (RJR Br. 32) that a ban of tobacco products "was not reasonably in the contemplation of the enacting Congress." But if, as we have shown, compelling new evidence establishes that the nicotine in tobacco products is intended to sustain addiction and for sedation, stimulation, and weight control—and if, as respondents assert, tobacco products cannot be marketed with a reasonable assurance of safety—the Act would require a ban. The fact that the legislators who voted for the 1938 Act did not anticipate that such evidence would come to light and that tobacco products would be covered by the Act as a result—or that some might have regarded a ban as undesirable even in those circumstances—is simply not relevant to

the statutory inquiry. Congress deliberately crafted broad definitions of "drug" and "device" in 1938, and "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale* v. *Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998).

2. In addition to disagreeing with FDA's judgment concerning whether tobacco products must be banned, respondents argue that FDA has misinterpreted several other provisions of the FDCA. Those criticisms are misguided.

a. Noting that a device is "misbranded" if "it is dangerous to health when used in the * * * manner * * * suggested in the labeling," 21 U.S.C. 352(j), respondents object (RJR Br. 27) that FDA did not explain why that provision is inapplicable to tobacco products. The reason is that, just as the benefits of some cancer treatments outweigh their health risks, the benefits of allowing tobacco products to remain on the market, subject to regulatory controls, outweigh the health risks of removing them from the market. They are therefore not "dangerous to health" within the meaning of that provision. Even if that provision were applicable, however, FDA would have discretion to decide that, given the danger to the health of addicted adults of removing tobacco products from the market, it should not be enforced against those products. *Chaney*, 470 U.S. at 835.[10]

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[10] For the same reason, there is no merit to respondents' argument (RJR Br. 30) that FDA has failed to comply with a section of the Act providing that, "[i]f [FDA] finds that there is a reasonable probability that a device * * * would cause serious, adverse health consequences or death, [FDA] shall issue an order requiring the [manufacturer] * * * to immediately cease distribution of such device." 21 U.S.C. 360h(e)(1)(A). FDA's finding that banning tobacco products would create greater dangers than leaving them on the market subject to regulatory controls makes that provision inapplicable. But even if it were applicable, FDA would have discretion not to issue a cease-distribution order. *Chaney*, 470 U.S. at 835. Although the provision uses the word "shall," FDA has interpreted it as permissive rather than mandatory. See 21 C.F.R. 810.10(a) (FDA "may issue a cease distribution and notification order"). FDA's interpretation is

b. Respondents contend (RJR Br. 28) that, because a device is misbranded if it fails to bear "adequate directions for use," and FDA has not required such directions for tobacco products, "it must be FDA's view that adequate directions for use of tobacco products cannot be written." FDA may grant an exemption from the adequate directions requirement, however, when it determines they are "not necessary for the protection of the public health." 21 U.S.C. 352(f). One such circumstance is when "adequate directions for common uses [of the device] are known to the ordinary individual." 21 C.F.R. 801.116. Because it is "common knowledge" how tobacco products are used, FDA reasonably decided an exemption was warranted. 61 Fed. Reg. at 44,465.

c. Finally, respondents argue (RJR Br. 28-29) that FDA failed to apply a misbranding provision that requires "adequate warnings against use * * * by children." 21 U.S.C. 352(f)(2). FDA concluded, however, that the familiar "Surgeon General's warnings" required by other federal statutes satisfy Section 352(f)(2). 61 Fed. Reg. at 44,465. That rationale is not "disingenuous," as respondents suggest. It reflects FDA's reasonable judgment that no warnings are likely to be effective for children, *id.* at 44,468, 44,511, and that the Surgeon General's warnings serve the purposes of Section 352(f)(2) as well as any that FDA could devise.

C. Tobacco-Specific Statues

Respondents concede (RJR Br. 36) that "the tobacco-specific statutes do not repeal any part of the FDCA or 'preempt' any action by FDA." They nevertheless submit (*ibid.*) that those very same statutes should preclude FDA from regulating tobacco products. Respondents are wrong.

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reasonable, because "shall" sometimes means "'should,' 'will,' or even 'may,'" *Gutierrez de Martinez* v. *Lamagno*, 515 U.S. 417, 432 n.9 (1995); because enforcement authority is usually discretionary; and because a cease-distribution order is only an interim step in a process that leads to a "recall order," which is itself discretionary, 21 U.S.C. 360h(e)(2)(A).

1. a. Respondents contend (PM Br. 37-41) that FCLAA precludes FDA regulation because FCLAA forecloses a ban on tobacco products, while FDA's determination that tobacco products are drug-delivery devices would necessarily lead to a ban. For three reasons, that contention is without merit. First, as we have shown, FDA's determination that tobacco products are covered by the Act as drug-delivery devices does not mean that they must be banned.

Second, FCLAA does not foreclose a ban on tobacco products. By its terms, FCLAA only prevents FDA from requiring any "statement relating to smoking and health, other than the statement required by" FCLAA itself. 15 U.S.C. 1334(a). Respondents' contention (PM Br. 38) that the "policy" statement in 15 U.S.C. 1331 precludes a ban finds no support in that provision's text, and it ignores the holding in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), that FCLAA "merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels," *id.* at 518, and that Section 1331 states not a broad policy of protecting the continued marketing of cigarettes, but a far more limited policy of "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations," *id.* at 514. See also *id.* at 534 (Blackmun J., concurring and dissenting); *Medtronic*, 518 U.S. at 488 (FCLAA preempts only a "limited set" of requirements).

Third, even if FDA's coverage determination were to result in a ban on the sale of tobacco products under the FDCA and Section 1331 were to preclude one, that still would not undermine FDA's coverage determination. It would simply mean that FCLAA (as the more specific statute) would preclude a ban, and FDA would therefore be required to adopt measures short of a complete ban to regulate tobacco products. Nothing in FCLAA, for example, would preclude FDA from continuing with its current regulatory program of pre-

venting sales of tobacco products to minors or from requiring safer ingredients or a safer filter.

b. Respondents further argue (PM Br. 41-42) that FDA's coverage determination is precluded by FCLAA because the FDCA requires FDA to impose labeling requirements, such as adequate directions for use and warnings for children, while FCLAA prevents FDA from imposing those requirements. As we have explained, however, FDA exempted tobacco products from the FDCA's adequate directions requirement, and it reasonably determined that the Surgeon General's warnings are sufficient warnings for children. See p. 16, *supra*.[11] In any event, to the extent that FCLAA precludes FDA from imposing particular restrictions on tobacco products that the FDCA otherwise would require, the more specific statute would govern and FDA would be limited to regulating tobacco products in other ways.[12]

2. Respondents contend (NACS Br. 14, 18-19) that FDA's coverage determination is precluded by ADAMHA because ADAMHA generally permits States to decide what measures to adopt to curb youth tobacco use, while FDA's tobacco regulations preempt state laws that are "different from, or in addition to," FDA's requirements. 21 U.S.C. 360k(a)(1). ADAMHA, however, simply conditions certain federal funding on the States' enactment of their own laws against tobacco use. Gov't Br. 47. It does not address whether FDA

[11] Respondents erroneously contend (PM Br. 42) that FCLAA precludes FDA from requiring tobacco-product labeling to bear the statement "Nicotine-Delivery Device for Persons 18 or Older." Because that statement simply informs consumers about the products' intended and lawful use, and does not contain any warning about the health dangers of tobacco use, it is not a statement "relat[ing] to smoking and health" within the meaning of 15 U.S.C. 1334(a). Even if it were, however, that would lead only to invalidation of that requirement. It would not affect the conclusion that tobacco products are drug-delivery devices under the FDCA.

[12] There likewise is no inconsistency between FDA's actions and the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. 4401 *et seq.*, since as respondents concede (UST Br. 31), it was modeled on FCLAA and contains the same basic requirements. Gov't Br. 46.

may conclude that tobacco products are drug-delivery devices and subject to federal regulation as well. Moreover, contrary to respondents' assertion (RJR Br. 46-47), FDA's regulations do not divest States of authority to regulate tobacco products. States are free to impose whatever requirements they choose when there is no parallel FDA requirement; and where there are federal requirements, the States may impose substantially similar ones. *Medtronic*, 518 U.S. at 496-497; 21 C.F.R. 808.1(d)(2). In addition, the FDCA authorizes FDA to exempt from preemption state laws that impose more stringent requirements than FDA's, 21 U.S.C. 360k(b), and FDA has done so on many occasions. And while respondents object to that regime as insufficiently sensitive to state interests (NACS Br. 18-19), an amici brief joined by 40 States concludes (Br. 19) that "FDA's authority to regulate tobacco products is authorized by law, and is a critically important part of the effort to limit the use of tobacco products by minors."

D. *Chevron* Deference

Respondents err in contending (RJR Br. 47-50) that this case should be resolved entirely outside the *Chevron* framework. As respondents note (RJR Br. 48), this case involves the construction of both the FDCA, which FDA enforces, and tobacco-specific statutes, which it does not. But that does not mean that the *Chevron* framework should be discarded. Instead, the Court should first decide under *Chevron* whether FDA's interpretation of the Act it administers is permissible. If the Court concludes that it is, the Court should then decide independently whether FDA's authority under the FDCA has been divested by the tobacco-specific statutes. *NASA* v. *FLRA*, 119 S. Ct. 1979, 1984-1985 (1999). As we have shown, FDA's interpretation is based on a permissible reading of the FDCA, and the tobacco-specific statutes do not withdraw FDA's authority.

Respondents similarly err in contending (RJR Br. 49) that the *Chevron* framework does not apply because FDA has

changed its position on whether tobacco products are covered by the Act. Under *Chevron*, a change in agency position is entitled to full deference, as long as the agency offers a reasoned analysis for the change. See 467 U.S. at 863-864; *Rust* v. *Sullivan*, 500 U.S. 173, 186-187 (1991); *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). FDA supplied such an analysis here. FDA adhered to its longstanding legal position that a finding of "intended" effects may be based on evidence other than manufacturer claims, and it found compelling new evidence that tobacco products are intended to be used to sustain addiction and for stimulation and sedation.

Finally, respondents argue (RJR Br. 47-48) that this case should be resolved against FDA at the first step of *Chevron*. The relevant indicia of congressional intent, however, do not come close to establishing that Congress "directly addressed the precise question at issue" and "unambiguously expressed [its] intent" that tobacco products fall outside the reach of the FDCA. 467 U.S. at 843. To the contrary, the text, legislative history, and administrative interpretation of the Act strongly support FDA's conclusion that, given the overwhelming evidence that the nicotine in tobacco products is intended to be used to sustain addiction and as a sedative, stimulant, and appetite suppressant, tobacco products are drug-delivery devices within the meaning of the FDCA. At the very least, FDA's conclusion is based on "a permissible construction" of the Act. *Ibid.*

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For the foregoing reasons and those in our opening brief, the judgment of the court of appeals should be reversed.

SETH P. WAXMAN
Solicitor General

OCTOBER 1999

APPENDIX

Section 801.4 of 21 C.F.R. states as follows:

§ 801.4 Meaning of "intended uses."

The words *intended uses* or words of similar import in §§801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

Section 801.5 of 21 C.F.R. states as follows:

§ 801.5 Medical devices; adequate directions for use.

Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines *intended use.* Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors.

(f) Route or method of administration or application.

(g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process.